SEP - 6 2001

Summary of Safety and Effectiveness
Liquichek™ Cardiac Markers Control LT

K012656

1.0 Submitter

Bio-Rad Laboratories
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Contact Person

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Date of Summary Preparation

August 7, 2001

2.0 Device Identification

Product Trade Name:	Liquichek™ Cardiac Markers Control LT
Common Name:	Enzyme Controls, (Assayed and unassayed)
Classifications:	Class I
Product Code:	75JJT
Regulation Number:	CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek™ Cardiac Markers Control LT
Bio-Rad Laboratories
Irvine, California

Docket Number: K980556

4.0 Description of Device

Liquichek™ Cardiac Markers Control LT is prepared from human serum with added constituents of human and animal origin, preservatives and stabilizers. The control is provided in liquid form for convenience.

5.0 Statement of Intended Use

Liquichek™ Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory procedures listed in the package insert.

6.0 Comparison of the new device with the Predicate Device

The new Liquichek™ Cardiac Markers Control LT claims substantial equivalence to the Liquichek™ Cardiac Markers Control LT currently in commercial distribution (K980556). The new Liquichek™ Cardiac Markers Control LT contains Homocysteine and Digitoxin and the current product does not. The new Liquichek™ Cardiac Markers Control LT does not contain CK Total, LD-1 Isoenzyme and the current product does.

Table 1. Similarities and Differences between new and predicate device.

Characteristics	Bio Rad Liquichek™ Cardiac Markers Control LT (New Device)	Bio Rad Liquichek™ Cardiac Markers Control LT (Predicate Device)
	Similarities	
Intended Use	Liquichek™ Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in the package insert.	Liquichek™ Cardiac Markers Control LT is intended for use as an assayed quality control serum to monitor the precision of an individual laboratory's specific cardiac marker procedures.
Form	Liquid	Liquid
Matrix	Human serum based	Human serum based
	Differences	
Storage (Unopened)	–20°C or colder until expiration date	-10 °C to –20°C until expiration date
Open Vial Claim At 2-8°C	Troponin-I and Homocysteine 10 days Myoglobin, CK-MB, and Digitoxin 20 days	CK, Total, CK-MB, LD-1 Isoenzyme 20 days Myoglobin, Troponin I, Troponin T 10 days
Analytes	Contains: Troponin-I, Troponin T, Myoglobin, CK-MB, Homocysteine and Digitoxin Does not Contain: CK Total, LD-1	Contains CK, Total, CK-MB, LD-1 Isoenzyme, Myoglobin, Troponin I, Troponin T Does not contain: Homocysteine and Digitoxin

7.0 Summary of Performance Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek™ Cardiac Markers Control LT. Product claims are as follows:

7.1 Open vial: Once the control material is thawed and opened, all analytes will be stable for 20 days when stored tightly capped at 2-8°C, with the following exceptions: Troponin I and Homocysteine will be stable for 10 days.

7.2 Do not refreeze the control once it has been thawed.

7.3 Shelf Life: Two years when stored at –20 °C or colder

Real time studies will be ongoing to support the shelf life of this product.

All supporting data is retained on file at Bio-Rad Laboratories.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 6 2001

Ms. Elizabeth Platt
Regulatory Affairs Manager
Bio-Rad Laboratories, QSD
9500 Jeronimo Road
Irvine, CA 92618

Re: K012656
Trade/Device Name: Liquichek Cardiac Markers Control LT
Regulation Number: 21 CFR 862.1660
Regulatory Class: I, reserved
Product Code: JJT, JJY
Dated: August 7, 2001
Received: August 13, 2001

Dear Ms. Platt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known): K012656

Device Name: **Liquichek™ Cardiac Markers Control LT**

Indications for Use:

An assayed quality control serum to monitor the precision of laboratory testing procedures for analytes listed in the package insert.

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓ or Over-the Counter use _____

Kevin Alexander for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012656